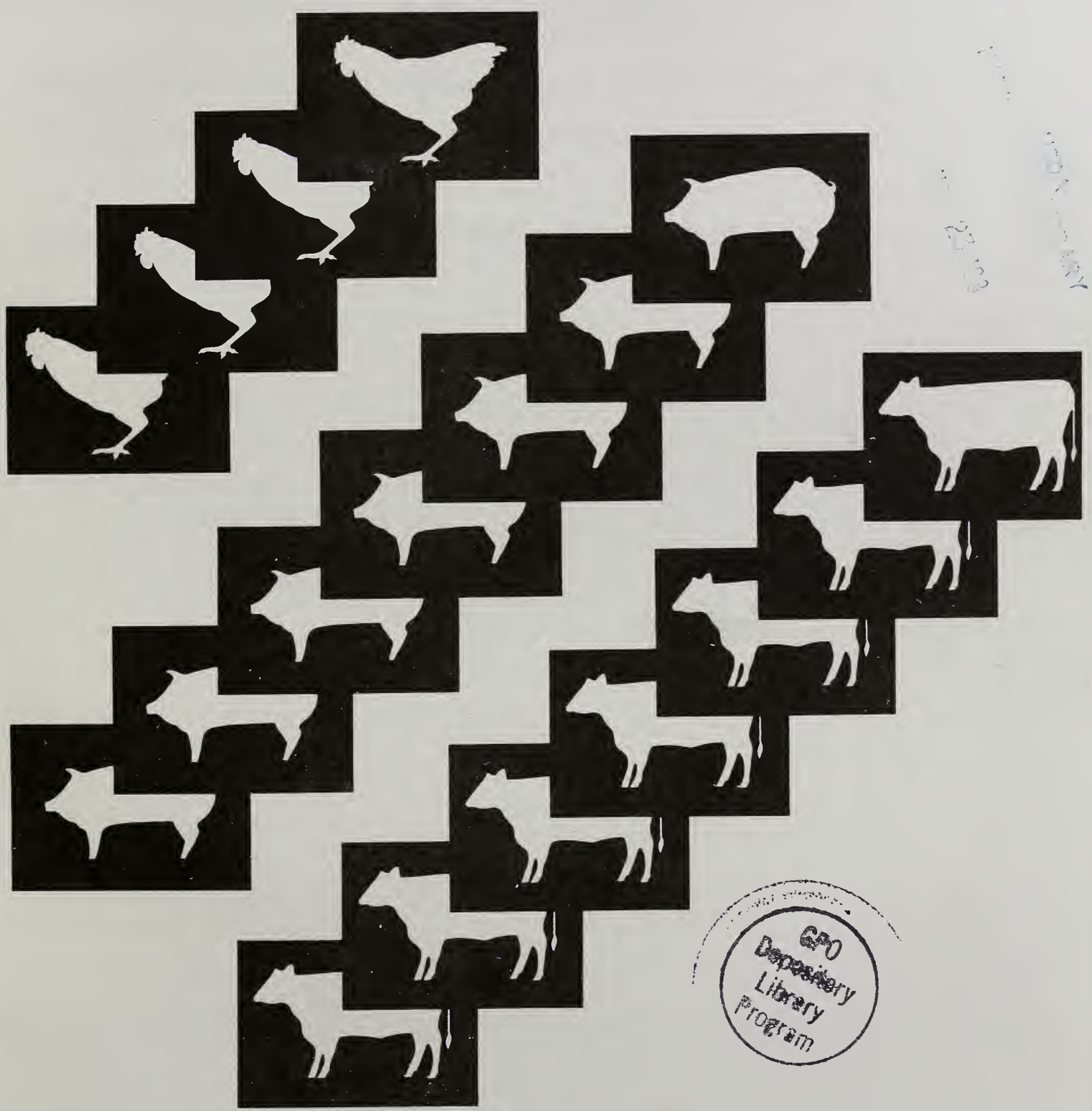
United States
Department of
Agriculture

Food Safety
and Inspection
Service

February 1 thru
March 31, 1993

Compilation of Meat and Poultry Inspection Issuances



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This publication covers issuances published during the period February 1 through March 31, 1993.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 4-93 | 2/9/93

MANDATORY NUTRITION LABELING

I. PURPOSE

This Notice provides Agency personnel and industry with interim label approval procedures and information for implementing the mandatory nutrition labeling regulations.

II. BACKGROUND

A. On January 6, 1993, the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration published the nutrition labeling regulations. These regulations will substantially change important aspects of food labeling and affect almost every food product sold in the United States.

B. FSIS's Food Labeling Division (FLD) and Product Assessment Division (PAD) are developing strategic plans to achieve a smooth transition for label assessment, review, and approval in accordance with the new regulations. Although the effective date for compliance with the regulations is July 6, 1994, companies may now begin modifying labels in accordance with the new requirements.

III. INTERIM PROCEDURES

All labels conforming to the nutrition labeling regulations must be submitted to FLD for review and approval. This heavy volume of labels, along with other types of labels currently reviewed and approved at the headquarters level, will absorb a significant amount of FSIS resources within the next 18 months. In order to ease the workload for both FSIS and the industry, FSIS has developed the following interim operating procedures for label approval.

A. Owners and operators of official establishments affected by the nutrition labeling regulations are encouraged to immediately familiarize themselves with the new rules.

DISTRIBUTION: Inspec. Offices T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID	NOTICE EXPIRES: 7-6-94	OPI: RP/FLD

B. On March 1, 1993, official establishments may begin to submit to FLD new labels that comply with the nutrition labeling regulations. Training of relevant FSIS staff is underway and will continue until that date. Labels submitted prior to March 1, 1993, will be handled as trained staff become available.

C. Official establishments are encouraged to submit one label application for a product produced in multiple establishments under the same ownership. The label must represent products with identical formulations, except that each label must bear the appropriate establishment number before use. Package sizes may vary.

D. Official establishments using labels and other labeling of products representing different brand names (private labeling), but which have identical formulations, may also submit one label application for approval. The label application must include a separate written request, signed by a responsible establishment management official, listing each such label, the date that each label was previously approved, and the approval number for each.

E. Official establishments which develop new labels for other than nutrition labeling are urged to take advantage of regulatory options for inspector-in-charge label approvals and generic label approvals. These are prescribed in sections 317.4(e) and 381.132(c) and sections 317.5(b) and 381.134(b) of the Meat and Poultry Inspection Regulations, respectively. Maximum utilization of these options will assist greatly in reducing the volume of labels received at the headquarters level and will allow use of such new labels by official establishments in a more timely manner.

IV. INFORMATION MATERIALS

A. A series of question and answer guides will be assembled and published as FSIS issuances to assist labeling applicants in the proper presentation of nutrition labeling requirements. FSIS requests that interested parties submit written questions for inclusion in the guides to either FLD or PAD, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

B. Instructional materials will be provided upon written request to FLD or PAD at the above address or by calling FLD at (202) 205-0042 or PAD at (202) 205-0080. These materials will include listings of mandatory and voluntary nutrients, an FSIS backgrounder, nutrient content claims definitions, and examples of nutrition formats with a diagram of new print requirements.

Deputy Administrator
Regulatory Programs

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE

10-93 | 3-5-93

TEMPORARY SUSPENSION AND/OR WITHDRAWAL OF INSPECTION SERVICES

I. PURPOSE

This notice clarifies the Food Safety and Inspection Service's (FSIS) policy on the temporary suspension and subsequent withdrawal of inspection services from any recipient or operator of an establishment which produces meat or poultry products under conditions and/or procedures that may endanger public health and safety.

II. BACKGROUND

It is FSIS's responsibility to ensure that establishments subject to Federal inspection comply with all applicable requirements of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), and produce only safe, wholesome, and properly labeled meat and poultry products in a sanitary environment. FSIS accomplishes this responsibility through inspection of plants' products, practices, and conditions that may effect those products and by undertaking enforcement actions as appropriate.

III. POLICY AND PROCEDURES

A. If, at any time, FSIS personnel determine that the operating practices or conditions of an establishment receiving inspection services are such that meat or poultry products prepared therein are or would be rendered adulterated in any particular, FSIS will:

1. Refuse to allow alleged adulterated meat or poultry products to be labeled, marked, stamped, or tagged as "inspected and passed."

DISTRIBUTION: Inspec. Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID

NOTICE EXPIRES:

OPI: RP/EED

2. Immediately retain, detain, or cause to be seized all alleged adulterated meat or poultry products produced under such conditions and/or procedures.

3. As promptly as circumstances permit, provide each recipient of inspection services and each individual responsibly connected with the establishment a written notice which includes:

a. A description of the alleged violations of the Acts and/or the regulations issued thereunder.

b. A description of the actions considered necessary to be taken by each recipient or operator of the establishment to (a) effect a permanent correction of the unacceptable conditions, (b) comply with the requirements of the Acts and/or regulations promulgated thereunder, and (c) eliminate the need to commence an action to withdraw inspection services.

c. A statement indicating that (a) there will be a suspension of inspection operations until permanent corrections of the unacceptable practices or conditions described have been achieved, and (b) if the applicant or operator of the establishment fails to eliminate the unacceptable practices or conditions described, FSIS intends to commence an action to withdraw inspection, in accordance with appropriate Uniform and Supplemental Rules of Practice as set forth in 9 CFR Part 335 and Part 381, Subpart W.

B. The provisions contained in this notice supersede the provisions contained in FSIS Directive 8830.1, Progressive Enforcement Action (PEA)--Stages I,II, and III, dated 3/01/91, when it has been determined that an establishment is producing products under conditions that may pose an immediate threat to public health and safety.

H. Russell Cross
Administrator

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

7330.1 | 2-24-93

SAMPLING FREQUENCIES FOR COOKED SAUSAGE PRODUCED UNDER A QUALITY CONTROL PROGRAM

I. PURPOSE

The purpose of this directive is to clarify how cooked sausages, produced under a quality control program, are sampled and what actions inspectors should take. This directive also cancels Part 18.24 (h)(1)(2)(i) of the MPI Manual. That Part of the manual is no longer consistent with the sampling frequencies and actions taken to monitor the levels of fat and added water in finished cooked sausage products produced under a partial quality control or total quality control program.

II. CANCELLATION

MPI Manual, Part 18.24 (h)(1)(2)(i)

III. [RESERVED]

IV. REFERENCES

FSIS Directive 8820.1, Revision 1, dated 3/1/91
FSIS Directive 8830.1, dated 3/1/91

V. BACKGROUND

Effective April 1988, sections 319.180 and 319.181 of the MPI Regulations were amended to provide for a maximum combination of fat and added water in frankfurters and similar cooked sausage products of 40 percent. The water limitation was removed; the fat limitation remained at 30 percent.

VI. POLICY

As required by MPI regulations, FSIS employees monitor the processing of cooked sausage products to assure that no adulterated or misbranded products are produced. Finished products are randomly sampled for laboratory analysis as scheduled by the Performance Based Inspection System (PBIS).

DISTRIBUTION: Inspection Offices, T/A Inspectors **OPI:** S&T/PPID
Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID

VII. **SAMPLING FREQUENCIES**

A. Currently, sampling frequencies for cooked sausage produced by establishments operating with or without a quality control (QC) program are scheduled by the PBIS. QC verification samples of cooked sausage are also collected when scheduled by PBIS and those sample results will be used to evaluate the process control of an approved QC program for cooked sausage.

B. Inspectors who intend to take corrective action regarding a QC program because of violative sample results should follow the procedures outlined in FSIS Directive 8820.1, Corrective Action System and FSIS Directive 8830.1, Progressive Enforcement Action.

If there any questions regarding this directive, please use the normal channels of contacting the Regional Office.

Deputy Administrator
Inspection Operations

CONTAMINATION RESPONSE SYSTEM (CRS)

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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,530.3	3-23-93

CONTAMINATION RESPONSE SYSTEM (CRS)

I. PURPOSE

This directive outlines procedures for FSIS organizations to follow when responding to a contamination incident when a particular residue is suspected or found in meat and poultry products. The CRS is a part of the FSIS Residue Program which is designed to detect, monitor, reduce, and control residues of animal drugs, pesticides, and other chemicals and contaminants in meat and poultry products.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

FSIS Directive 10,530.1, National Residue Program
Federal Meat Inspection Act
Poultry Products Inspection Act
MPI Regulations, Parts 309, 310, 311, 318, 327; sections 354.130, 381.60, 381.70-381.80, 381.91, 381.95, and 381.197
Report on the PCB Incident in the Western United States, USDA, FSIS, January 1980

V. ABBREVIATIONS AND FORMS

The following will appear in their shortened form in this directive:

ADA - Assistant Deputy Administrator
AIIS - Automated Import Information System
AM - Administrative Management
AMS - Agricultural Marketing Service
ASD - Administrative Services Division, AM
APHIS - Animal and Plant Health Inspection Service

DISTRIBUTION: Inspection Offices, T/A Inspectors
Plant Management, T/A Plant Management, TRA,
ABB, PRD, AID

OPI: S&T/REPD

CD - Chemistry Division, S&T
CP - Compliance Program, RP
CRS - Contamination Response System

DA - Deputy Administrator

EPA - Environmental Protection Agency
EEPS - Epidemiology and Emergency Programs Staff, IMP, IO

FDA - Food and Drug Administration
FMIA - Federal Meat Inspection Act
FOD - Field Operations Division, CP, RP
FPD - Foreign Programs Division, IP
FSIS - Food Safety and Inspection Service

IFO - Import Field Office, IP
IID - Import Inspection Division, IP
ILA - Information and Legislative Affairs Staff
IMP - Inspection Management Program, IO
IO - Inspection Operations
IP - International Programs
IRSP - Import Residue Sampling Plan

MD - Microbiology Division, S&T
MOU - Memorandum of Understanding

OSCAR - On-Site Center for Action Response

PDD - Program Development Division, IP
POE - Port of Entry
PPIA - Poultry Products Inspection Act
PSB - Program Services Branch, ASD

QA - Quality Assurance
QC - Quality Control

ROS - Residue Operations Staff, IMP, IO

RP - Regulatory Programs
RPB - Residue Planning Branch, S&T
RVIS - Residue Violation Information System

S&T - Science and Technology
SDSD - Statistics and Data Systems Division, S&T
SRC - Standing Residue Committee, IP
SVMO - Supervisory Veterinary Medical Officer

VMO - Veterinary Medical Officer

WBC - Washington-Based Center

FSIS FORM 10,000-2 - Domestic Laboratory Report
FSIS Form 10,530-1 - Domestic Requested Residue Sample Program

VI. DEFINITIONS

A. **CRS Headquarters Team.** A team of all staffs in FSIS Headquarters involved in CRS cases that is managed by the Director, EEPS. This team represents various units such as ROS, RPB, CD and SDSD. Other units in USDA, such as AMS and APHIS, or other government agencies, such as FDA and EPA, are also represented, as needed.

B. **On-Site Center for Action Response.** This is a facility local to the CRS case, from which a team of headquarters and field specialists, organized and managed by the Director of EEPS, facilitate the investigation at the action stage.

C. **Potential Violation.** A tissue residue concentration for CRS compounds, insufficient for product condemnation but sufficient to suggest a developing or ongoing residue problem in animals or product from the same source. This concentration is 80% to 100% of the tolerance or action level, unless otherwise defined by FSIS on an individual compound basis.

D. **Residue Violation Information System.** A nationwide, interagency computer information system designed to provide data about residue violations in livestock and poultry slaughtered in the United States.

E. **Violation.** A residue finding exceeding the established tolerance, action level, or other FSIS defined residue limit.

VII. POLICY

A. Under the FMIA and the PPIA, FSIS is responsible for carrying out an inspection program to assure consumers that meat and poultry products distributed to them are safe, wholesome, and accurately labeled. An integral part of the inspection program is the FSIS Residue Program. The FSIS Residue Program collects samples of meat and poultry products at domestic slaughter establishments under FSIS and State inspection authority. These samples are then analyzed for unacceptable levels of residues,

either by one of the three FSIS field laboratories, by an accredited laboratory or by a laboratory under contract to FSIS.

B. The goal of the FSIS Residue Program is to protect the consumer from meat and poultry products that contain chemical contaminants. Two other agencies play major roles in protecting the public from residues left in food by agricultural chemicals, animal drugs and environmental contaminants. The EPA regulates pesticides that can be used in food production and other industrial chemicals that have the potential for contaminating food. EPA sets the tolerances for pesticides. The FDA regulates and inspects foods other than meat and poultry and regulates animal feeds. This includes establishing tolerances for residues of animal drugs, environmental contaminants and natural contaminants in edible tissues of food animals. FSIS and FDA work cooperatively with State meat and poultry inspection programs to achieve mutual objectives in residue control and prevention. A major part of the FSIS Residue Program is the Contamination Response System.

VIII. CONTAMINATION RESPONSE SYSTEM

A. The CRS is a system for implementation in the event of a chemical contamination crisis. Mechanisms are included for rapid response to suspicion or discovery of tissue residues and other contaminants with the potential to cause widespread adulteration of meat and poultry products. The CRS includes procedures for expediting communication, information collection, evaluation, and decisionmaking. The most commonly identified residues are among the agricultural pesticides and environmental contaminants.

B. When a potential or known residue crisis is identified under the FSIS Residue Program, RPB activates the CRS case in consultation with EEPS. The CRS utilizes the resources of all relevant FSIS headquarters and field units to resolve drug and pesticide problems promptly. The CRS demands a concerted effort by all programs within FSIS to assure that all aspects of the CRS are efficiently managed and fully staffed during the three phases of a CRS crisis.

C. The Administrator has designated the Director of EEPS to coordinate and direct the activities of the CRS Headquarters team. Each participating headquarters division is required to provide two representatives. One representative is assigned to the Washington-Based Center to respond to any residue action phase. The other representative is assigned to OSCAR which is activated only during the action phase.

D. The Director of EEPS establishes a WBC for Action Responses staffed by an interdisciplinary FSIS CRS team that directs follow-up actions. The Director also establishes OSCAR. The WBC

and OSCAR FSIS specialists coordinate operations and maintain communications with the region, FSIS headquarters, other government agencies, industry and the news media.

IX. PHASES OF CRS

A. There are three phases of Agency response within CRS: Warning Condition, Alert Condition, and Action Condition. Each of these phases, further divided into three distinct parts called declaration, objectives, and organization, are discussed below.

B. These phases of CRS are based on the characteristics of the contaminant, extent of animal or product exposure, and potential for suspect product to enter commerce. Most case actions originate from FSIS residue analyses. Cases also result from nonprogram tests and knowledge of chemical spills or product exposure that have the potential to affect food animals and related products. The Director, EEPS, directs and coordinates all phases.

C. The three phases are as follows:

1. **WARNING CONDITION.** This phase is a response to an isolated incident usually involving a single farm or lot of product and one contamination source. Little or no suspect meat and poultry products are traceable in commerce or are likely to enter commerce.

a. DECLARATION: Declared by RPB in concert with EEPS any time a laboratory finding for a CRS compound is a potential violation or violation. The Directors of EEPS and ROS are available for consultation with other units. The Director, EEPS, will provide directions as necessary.

b. OBJECTIVES:

(1). Collect data to determine if the violation comes from a single animal or multiple animals.

(2). Collect data to determine if there is one producer or several producers with violations.

(3). Collect followup data and samples from the producer.

c. ORGANIZATION:

(1). RPB receives potential violation or violation information from FSIS Laboratories and consults with EEPS.

(2). RPB will call AMS, ROS, FDA, EPA and Regional Office of the State in which the producer maintains a business.

(3). RPB will notify by mail appropriate persons in FDA, USDA and EPA of the CRS case and provide them with a copy of the laboratory form.

2. **ALERT CONDITION.** The second phase is a response to an isolated incident usually involving multiple farms or lots of product and one or more contamination sites. A limited amount of suspect meat and poultry products may have entered commerce and may continue to enter commerce until the sources have been identified and controlled. (This is the minimum condition in polychlorinated biphenyl cases.)

a. DECLARATION: The CRS Chairperson declares an Alert Condition on recommendation of the Director, EEPS, in concert with Director, RPB. At this point, the Director, EEPS, maintains liaison with the FSIS Deputy Administrators and equivalent officials from cooperating agencies.

b. OBJECTIVES:

(1). To collect data to determine if the violation involves product in commerce which would lead to an Action Condition.

(2). To stop the future entrance of contaminated product into commerce.

(3). To identify other sources and lots of contaminated product.

c. ORGANIZATION:

(1). RPB receives potential violation or violation information from FSIS Laboratories and consults with EEPS.

(2). RPB will call AMS, ROS, FDA, EPA and Regional Office of the State in which the producer maintains a business.

(3). RPB will notify by mail appropriate persons in FDA, USDA and EPA of the CRS case and provide them with a copy

of the laboratory form.

3. **ACTION CONDITION.** The final phase is a response to an incident involving multiple farms or product lots and one or more primary or secondary sources of contamination. Contaminated product is likely in commerce at numerous locations. The concentration of residue present and level of toxicity also influences overall urgency and need for action response. The Action Condition requires special activities and temporary reorganization of traditional lines of communication.

a. DECLARATION: The CRS Chairperson declares an Action Condition following the advice of the CRS Headquarters Team Coordinator and the concurrence of the Administrator.

b. OBJECTIVES:

(1). To determine if potentially contaminated products and livestock/poultry sent to slaughter are in fact contaminated.

(2). To prevent production and distribution of contaminated products.

(3). To recall or otherwise control contaminated products in the marketplace.

(4). To assure proper disposal of contaminated products.

(5). To provide accurate and timely information to the general public, industry, and other participating government agencies as needed.

c. ORGANIZATION:

(1). Washington-Based Center for Action Response.

(a). Responsibilities:

(i). Plans and directs the headquarters and field level action response.

(ii). Informs Administrator of progress.

(iii). Provides technical and scientific support to OSCAR and all headquarters offices.

(iv). Maintains communications with headquarters offices of other involved agencies.

(b). Staffing:

(i). One or more members from each participating headquarters FSIS division, staff or branch.

(ii). Each member may not be required to participate full time; however, if necessary, it will be the members' highest priority during the Alert and Action Condition cases.

(iii). Other agencies may provide members if necessary.

(2). On-Site Center for Action Response

(a). Responsibilities:

(i). Investigate and delineate the problem.

(ii). Coordinate and direct the testing of potentially exposed livestock or product; report and interpret test results.

(iii). Coordinate recalls of contaminated product.

(iv). Assist in systematic and appropriate disposal of condemned product.

(v). Provide accurate information to headquarters on the situation.

(vi). Provide accurate information to the public.

(vii). Establish and maintain contact with State and local offices of other agencies, the media, and affected local industries.

(b). Staffing. OSCAR will be staffed by at least one CRS Headquarters team member from each assigned FSIS program. Members will be relieved from their normal duties while serving at OSCAR and will report to the OSCAR Coordinator who is responsible to the Director, EEPS. The OSCAR staff will include:

(i). OSCAR Coordinator (IO, EEPS)

(ii). Residue Operations Staff

Officer (IO, ROS)

(iii). Support Staff Manager (IO, EEPS)

(iv). Laboratory Advisor (S&T, FSIS Laboratories)

(v). Chemistry Advisor (S&T, CD)

(vi). Residue Specialist (S&T, RPB)

(vii). Epidemiologist (IO, EEPS)

(viii). Compliance Representative from Hq. and/or Field Level Supervisor (RP,CP)

(ix). Information Specialist (EAS)

(x). Equipment Manager (ASD)

(xi). Regional Residue Staff Officer (IO)

(xii). FSIS Field Supervisor (IO)

(xiii). Supervisor from participating Federal or State agencies on a voluntary basis.

(c). Support Staff. The Support Staff Manager is responsible for staffing OSCAR with Program Assistants, computer operators, and clerk typists who have sufficient FSIS experience to function effectively with limited briefing. Personnel will be detailed to OSCAR from FSIS regional offices, area offices, or headquarters, as needed. Investigative and control actions are facilitated under OSCAR by the assigned representatives and specialists.

(d). Site Selection. The Director, EEPS, selects the site based upon the following criteria:

(i). Availability of adequate space.

(ii). Convenience to FSIS field offices, State authorities, or other cooperating agencies.

(iii). Proximity to emergency site(s).

(iv). Ability to acquire and install necessary equipment.

(e). Equipment. ASD specialists provide the equipment and facilities necessary to establish operations and set up OSCAR. Some items may be brought with the team. However, it may be necessary to rent other pieces of equipment locally. Necessary equipment includes the following:

(i). Telephone lines.
(ii). Conference call system.
(iii). Copy machine.
(iv). Telecopier.
(v). Portable computer.
(vi). Typewriters.
(vii). County and State maps.
(viii). Cars.
(ix). Flip charts.
(x). Office materials, including files.

X. CRS RESPONSIBILITIES. The responsibilities of both the headquarters and field personnel are instrumental in responding to a CRS incident. The following sections discuss those responsibilities.

A. **Headquarters Personnel.** The DA, IO, has been delegated as CRS Chairperson with overall responsibility for CRS activities. Each deputy area is represented as a part of the CRS Headquarters Team and the WBC for Action Response.

B. **Other Agencies.** Other USDA agencies, such as AMS, APHIS, and other governmental agencies, such as FDA and EPA, located in the Washington, DC area are included in the CRS Headquarters Team and the WBC for Action Response.

C. **Reporting Responsibilities.** Each participating FSIS headquarters unit is responsible for maintaining a record of costs related to the emergency situation in accordance with FSIS Directive 9050-1, Cost Accounting System for Actual and Potential Recalls and Contamination Response Cases, dated June 14, 1983. This information is compiled on FSIS Form 9050-1, Potential and Actual Recalls/CRS Incidents Cost Approval Report, dated November 1984. Each participating division and staff will mail the reports to EEPS on a weekly basis.

1. **Inspection Operations**

a. **Deputy Administrator.** The Administrator has designated the DA of IO as CRS Chairperson with overall Agency responsibility for CRS activities.

b. **Inspection Management Program.** The ADA, IMP, is responsible for providing general guidance to ROS and EEPS.

(1). **Epidemiology and Emergency Program Staff** - General Responsibilities:

(a). Serves as coordinator and member of CRS Headquarters Team.

(b). Receives telephone and written notification from RPB for new CRS cases initiated by RPB.

(c). Receives information concerning residue-related accidents, natural disasters, and other incidents suspected to have caused chemical residues in animals and/or products. Sources providing this information include ROS, RPB, Emergency Planning Office of Policy Evaluation and Planning Staff, CP, other government agencies, industry, consumers, or news media.

(d). Receives a copy from FSIS Laboratories of each completed FSIS Form 10,000-2 (form and completion instructions shown in Attachment 5) which reports test results for samples collected under CRS cases.

(e). Recommends to RPB initiation of new CRS cases based upon reports to EEPS of incidents suspected to have caused chemical residues in animals and/or products.

(f). Meets with CRS Chairperson and recommends Alert or Action designation for qualifying CRS cases.

(g). Maintains case file on each CRS case.

(h). Directs, coordinates, and evaluates progress of all CRS cases through contact with regional offices and CRS Headquarters Team Members and other State and Federal agencies as necessary. The degree of EEPS interaction extends from tracking of the region's progress in uncomplicated warning cases until control measures are in effect for full-time management of OSCAR and the WBC for Action Response under the Action Condition.

(i). Informs CRS Chairperson of significant events in Alert and Action cases on a continual basis.

(j). Requests assistance from CRS Chairperson in maintaining liaison with comparable level EPA and FDA officials during Action cases as needed.

(k). Directs the submittal of cost accounting records on a case-by-case basis, and maintains and compiles such reports received from other FSIS units involved in CRS cases.

(1). Maintains EEPS cost accounting records for Alert and Action cases.

(2). Action Condition Responsibilities:

(a). Schedules meeting of CRS Headquarters Team immediately upon learning of any situation warranting consideration for Alert and Action cases.

(b). Meets with CRS Chairperson and recommends approval of Action Condition for cases designated by CRS Headquarters Team.

(c). Schedules emergency meeting of CRS Headquarters Team to plan strategies, upon designation of Action cases by the CRS Chairperson. Informs CRS Chairperson of proposed plan and obtains necessary clearances.

(d). Directs and coordinates activities of CRS Washington-Based Center for Action Response.

(e). Directs and coordinates OSCAR.

(i). Holds briefings and planning sessions at OSCAR with other OSCAR members, local FSIS officials and other agencies, industry, and consulting organizations participating in the Alert and Action cases.

(ii). Coordinates local FSIS actions and serves as primary OSCAR contact with the CRS Headquarters Team and the CRS Chairperson.

(f). Closes, with approval of CRS Chairperson, the OSCAR and Washington-Based Center for Action Response when the respective Action Condition objectives have been met.

(g). Documents the case when closed.

(h). Prepares interim and final reports on epidemiological investigations conducted.

(2). **Residue Operations Staff** - General Responsibilities:

(a). Serves as a member of CRS Headquarters Team.

(b). Provides procedural guidance to regions directly, through referral or after consultation with EEPS.

(c). Participates in approval process for special surveys and other special procedures that have significant impact upon field activities.

(d). Receives information during normal day-to-day communications about industrial, farm, and packing plant accidents, natural disasters, and other incidents suspected to cause chemical residues in animals and/or products. Sources providing this information include regional offices, Emergency Planning Office of the Policy Evaluation and Planning Staff, CP, other government agencies, industry, consumers or news media.

(i). Contacts EEPS for guidance.

(ii). Follows CRS Headquarters Team plan provided by EEPS.

(e). Maintains ROS cost accounting records for Alert and Action cases and submits to EEPS.

(2). Action Condition Responsibilities:

(a). Notifies regional offices immediately when an Action case is declared by the CRS Chairperson.

(b). Maintains communication and effectively utilizes inspection and supervisory field personnel for implementation of CRS Action Plan.

(c). Participates as member of OSCAR to meet CRS objectives.

2. **Science and Technology**

a. **Deputy Administrator.** The DA is responsible for providing statistical support, designing CRS testing programs, performing chemical analysis of samples, reporting and interpreting analytical results, and providing guidance to IO.

b. **Assistant Deputy Administrator, Scientific Support.** The ADA assures that statistical support and CRS testing program results are performed and maintained. Provides guidance to IO as necessary.

c. **Assistant Deputy Administrator, Technical Support.** The ADA assures that the chemical samples are analyzed and analytical results are reported and interpreted. Provides guidance to IO as necessary.

(1). General Responsibilities:

(a). Serves as a member of CRS Headquarters Team.

(b). Verifies and provides, on a priority basis, a copy or equivalent information to RPB and EEPS of each completed FSIS Form 10,530-1, which reports a CRS case warning level or higher monitoring test result for residues included under CRS.

(c). Verifies and provides, on a priority basis, a copy or equivalent information to RPB or EEPS for each completed FSIS Form 10,000-2, which reports test results for residues included under CRS.

(d). Provides CRS Headquarters Team with assistance concerning FSIS laboratory analytical capabilities, scheduling of sample analyses, laboratory contacts for receipt of samples during off duty hours and approving and scheduling overtime work in laboratories.

(e). Maintains FSIS Laboratories cost accounting records for Alert and Action Condition cases and submits to EEPS.

(2). Action Condition Responsibilities:

(a). As the designated OSCAR representative, consults with the CRS Headquarters Team for briefing.

(b). Schedules travel to OSCAR.

(c). Assembles background information as appropriate.

(d). OSCAR representative works closely with the FSIS laboratories to accomplish the following:

(i). Provides maximum FSIS laboratory capability for residue of interest.

(ii). Requests for non-validated methods a QA plan and QC instructions from CD.

(iii). Notifies PSB, ASD, in Minneapolis and obtains guidance for procurement needs.

(iv). Completes procurement specification.

(v). Completes bid solicitation process.

(vi). Requests PSB, ASD, to award contract.

(vii). Develops sample management plans.

(viii). Prepares specialized sample preparation and submission instructions.

(ix). Establishes data acquisition and reporting system in cooperation with SDSD.

(e). Coordinates the allocation and submission of samples to a specific FSIS or contract laboratory.

(f). Coordinates the receipt and distribution of analytical results from the representative laboratories to OSCAR by electronic transmission, if available.

e. **Residue Planning Branch**

(1). General Responsibilities:

(a). Serves as a member of CRS Headquarters Team.

(b). Receives a copy or equivalent information from FSIS Laboratories and contract laboratories of each completed FSIS Form 10,530-1, which reports warning level or higher monitoring test results for residues included under CRS.

(c). Receives a copy or equivalent information from FSIS Laboratories and contract laboratories of each completed FSIS Form 10,000-2, which reports test results for residues included under CRS.

(d). Receives information concerning residue-related accidents, national disasters, and other incidents suspected to have caused chemical residues in animals and/or products. Sources providing this information include other government agencies, industry, consumers or the news media.

(e). Reviews laboratory results and resolves with FSIS Laboratories, CD, or other units, as applicable, any questions on interpretation.

(f). Activates, in consultation with EEPS, on CRS case.

(g). Initiates new CRS cases from laboratory results and reports of residue contamination that meet criteria for Warning designation.

(h). Consults and advises EEPS on new or ongoing cases that warrant consideration for Alert or Action designations.

(i). Notifies the designated contacts for new CRS cases of test results, known case history and CRS response designations. This information will be provided by telephone and in writing to:

(i). EEPS, IO

(ii). ROS, IO

(iii). Regional Office, IO, for region of the State where the producer is located.

(iv). Compliance Program, RP (in writing only).

(v). EAS

(vi). FDA, Center for Veterinary Medicine.

(vii). FDA, Division of Epidemiological and Emergency Operations.

(viii). AMS, Poultry Grading Branch

(ix). AMS, Poultry Division (in writing only).

(x). EPA, Office of Pesticide and Toxic Substances.

(j). Develops sampling program in cooperation with SDSD for EEPS, as appropriate.

(k). Interprets results of sampling programs for EEPS in cooperation with SDSD.

(l). Updates toxicology and metabolism information.

(m). Requests EPA or FDA, as applicable, to develop residue guideline levels, action levels, or tolerances when needed to determine product dispositions.

(n). Maintains RPB cost accounting records for Alert and Action cases and submits to EEPS.

(2). Action Condition Responsibilities:

(a). Assembles available background material on the case including history, toxicology, compound characteristics, sampling plans, procedures, and test results.

(b). In consultation with SDSD and EEPS, prepares sampling plans.

(c). In consultation with CD, updates the toxicology and metabolism information on the subject compound.

(d). Designated OSCAR representative:

(i). Schedules and performs travel to OSCAR.

(ii). Participates in initial OSCAR meeting.

(iii). Communicates needs to RPB CRS Headquarters Team members.

(iv). Provides OSCAR with sampling plans, procedures and related information, as appropriate.

(v). Maintains recordkeeping in conjunction with RPB CRS Headquarters Team member.

f. **Chemistry Division**

(1). General Responsibilities:

(a). Serves as a member of CRS Headquarters Team.

(b). Initiates survey to identify Federal and State laboratories with required analytical capability if crisis exceeds FSIS capacity.

(c). Identifies accredited and non-accredited laboratories with required analytical capability and establishes capacity.

(d). Consults with and provides a statement of analytical capability to EEPS, RPB and FSIS Laboratories when a satisfactory analytical method is not available in the FSIS laboratories.

(e). Acts as liaison with other Federal government or contract laboratories in setting up analytical protocols, assessing results, and reporting to EEPS or RPB.

(f). Maintains CD cost accounting records for Alert and Action cases and submits to EEPS.

(2). Action Condition Responsibilities:

(a). Consults with the CRS Headquarters Team as the designated OSCAR representative.

(b). Schedules travel to OSCAR.

(c). Assembles background information, as appropriate.

(d). Conducts a literature search and develops or adopts a satisfactory analytical method, if a satisfactory analytical method is not available.

(e). Sets up and operates a QA program. This activity could be initiated and operating within 48 hours for a residue with an established, satisfactory analytical method. If none exists, item (d). above must be completed first.

(f). Contacts accredited laboratories to determine availability and sample capacity for the specific need.

(g). Evaluates non-accredited laboratories for temporary approval. The estimated time required to evaluate each new laboratory using existing analytical methodology is a minimum of 1 week.

3. **Regulatory Programs**

a. **Deputy Administrator.** The DA is responsible for providing guidance in obtaining samples from distribution channels to determine if product is violative, reviewing records pertaining to shipments of allegedly violative products, and assigning compliance personnel to assist in CRS areas, when necessary.

b. **The Assistant Deputy Administrator, RP, Compliance Program.** The ADA for CP is responsible for providing general guidance to assure implementation of the following activities related to CRS.

(1). General Responsibilities:

(a). Serves as a member of CRS Headquarters Team.

(b). Provides technical guidance to CRS Headquarters Team.

(c). Maintains CP cost accounting records for Alert and Action Condition cases and submits to EEPS.

(2). Action Condition Responsibilities:

(a). Serves as a member of OSCAR to meet CRS objectives.

(b). Consults with CRS Headquarters Team and provides technical guidance.

(c). Schedules travel to location of OSCAR, as necessary.

(d). Assembles background information.

(e). Obtains specimens as needed from distribution channels to determine if product is violative.

(f). Reviews all plant records pertaining to shipments of allegedly violative products.

(g). Assigns additional compliance personnel when necessary to assist in affected area(s).

(h). Coordinates voluntary recalls and reviews and executes detentions as necessary.

(i). Collects all records regarding reviews, persons contacted, and product dispositions, and provides records to OSCAR or CRS Headquarters Team, as appropriate.

(j). Maintains an integrated system of recordkeeping in conjunction with CRS Headquarters Team.

4. **Information and Legislative Affairs Staff**

a. **Staff Director.** The Staff Director is responsible for liaison activities between FSIS and the general public and between FSIS and Congress during CRS actions by promptly providing concise factual information as needed.

(1). General Responsibilities:

(a). Serves as a member of CRS Headquarters Team.

(b). Maintains ILA cost accounting records for Alert and Action Condition cases and submits to EEPS.

(2). Action Condition Responsibilities:

(a). Consults with CRS Headquarters Team for briefing as the designated OSCAR representative.

(b). Schedules travel to OSCAR.

(c). Assembles background information as appropriate.

(d). Sets up specific area for media briefings and other information activities.

(e). Creates a file of the incident which will include a chronology of the incident and relevant facts.

(f). Prepares briefing papers for USDA officials if announcements to the public are necessary.

(g). Identifies and contacts local media.

(h). Maintains a record of daily information activities.

(i). Serves as primary media spokesperson at OSCAR.

5. **Other FSIS Units**

All other units are responsible for any participation determined necessary by the CRS Chairperson to control or contain a residue hazard and prevent contaminated foods from reaching the public.

D. **Field Personnel** - The Regional Directors, Area Supervisors, Circuit Supervisors and the Inspectors in Charge respond to CRS activity, receiving their instructions from this directive and from the Director of EEPS, if necessary. The Regional Residue Staff Officer has numerous responsibilities and contacts, internal and external to the Agency in the CRS area, as outlined below.

E. **Reporting Responsibilities.** Each participating FSIS field unit is responsible for maintaining a record of costs related to the emergency situation in accordance with FSIS Directive 9050.1, Cost Accounting System for Actual and Potential Recalls/CRS Incidents Cost Approval Report, dated November 1984. Each participating field unit will mail the reports to EEPS each week.

1. **Regional Residue Staff Officer** - General Responsibilities:

a. Receives a copy of completed FSIS Form 10,530-1 having actionable residue test results from specimens collected within the region from the official laboratory. The Regional

Residue Staff Officer maintains listings of tolerances, action levels, and potential violation levels provided by RPB for use in the regional office.

b. Receives a copy of completed FSIS Form 10,530-1 having residue results from specimens collected within the same region from the official laboratory. Generally, all FSIS Form 10,000-2 results require followup action.

c. Identifies laboratory copies of forms for specimens collected within the region from owner/producers located in other regions.

(1). Immediately notifies by telephone the Regional Residue Staff Officer in the region where the owner/producer is located. This office has primary responsibility for followup action with the owner or producer and immediately contacts the laboratory for a copy of the laboratory report, if not received.

(2). Maintains interregional communications as needed to expedite followup actions.

d. Requests the official laboratory to provide, as needed, copies of test results for animals or products shipped out of the region for slaughter and sampling.

e. Receives, for new CRS cases, a telephone call from RPB that:

(1). Confirms the test results.
(2). Assigns the case number.
(3). Identifies the CRS response level.
(4). Provides and explains special procedures.

f. Uses residue results to determine product dispositions and controls over other products and animals from the same source.

g. Receives information about industrial, farm and packing plant accidents, natural disasters, and other incidents suspected of causing chemical residues in animals and/or products. Sources providing this information include FSIS area offices, other government agencies, industry, consumers or the news media.

(1). Contacts EEPS for guidance

(2). Follows plan provided by EEPS.

h. Implements new CRS case as follows:

(1). Assigns all regional case numbers via an automated data system.

(2). Notifies contacts for CRS cases within 8 working hours of RPB notification. Maintains communication with the designated contacts, as needed, during the course of the case investigation and evaluation. (The Regional Director can delegate telephone notifications to the Area Supervisors on a case-by-case basis, provided delays do not result and the Area Office has all necessary background information.) Notifies promptly, by telephone, the industry and government contacts listed below.

(a). Area Supervisor in areas where slaughter or processing of suspect animals or product has occurred or is likely to occur.

(b). Supervisory Veterinary Medical Officer of plants where slaughter of suspect animals or products has occurred or is likely to occur.

(c). Owner or producer of suspect animals or products. Send letter by registered mail.

(d). Integrated operation.

(e). State Official responsible for State interactions with producer in State which owner or producer is located.

(f). FDA Representative in FDA District where the owner or producer is located.

(g). Regional EPA Representative in the EPA Region where the owner or producer is located (for pesticides and industrial contaminants only).

(h). AMS - Egg Products Inspection Division Regional Representative and other AMS commodity contract representatives.

(i). Special contacts as determined by the Regional Director and the EEPS.

(3). Informs contacts of the following:

(a). CRS case number.

(b). Compound discovered or suspected.

(c). Animal or product in which residue was discovered and/or a description of the possible contamination incident.

(d). Amount of residue detected or suspected.

(e). Date and location of the sample collection or the possible contamination incident.

(f). Response level and action it entails.

(g). Names of the other organizations contacted.

(h). Request for the owner/producer to notify the FSIS regional office where and when animals will be brought to slaughter.

(i). Need to increase sampling of future lots.

(j). Need, if applicable, to immediately retain any and all related product at official establishments.

(k). Need to identify other species which may have been affected.

(4). Informs FDA contact of any "POSSIBLE REPEAT VIOLATOR."

(5). Requests all contacts to:

(a). Coordinate their actions.

(b). Provide case information as soon as available, by telephone, with written backup as needed. Request the producer to provide information during the initial telephone call including:

(i). Explanation for presence of the residue.

(ii). Farm layout and species present.

(iii). Integration status.

(iv). When, where and lotting for animals scheduled for slaughter.

(v). Consultants who will be or have been contacted.

(6). Provides the regions with written guidelines through ROS to assist in preparation of this correspondence.

(7). Distributes a copy of the producer notification letter and related laboratory form to each of the contacts notified by telephone.

i. Relays ongoing situation information to EEPS and other FSIS units as determined by the Director, EEPS, in concurrence with ROS.

j. Reports results of ongoing testing to designated contacts and obtains updates on case activities.

k. Reports information resulting in case closure.

(1). Makes recommendation to EEPS when test results and case histories show that the problem is corrected and the disposition of suspect product and animals have been made.

(2). Notifies the designated contacts by telephone.

(3). Prepares a closeout letter to the producer and sends copies to the other contacts, on the advice of EEPS.

(4). Consults with the EEPS before closing Alert and Action cases.

l. Compiles cost accounting records for regional office and subordinate units as covered in FSIS Directive 9050.1 for CRS cases requiring Alert or Action cases. Submits records to EEPS weekly.

5. **Area Supervisor -** General Responsibilities:

a. Coordinates collection and maintenance of case histories, product identification and control, and follow-up sampling in accordance with Attachment 3 and special directions from the region.

b. Communicates case progress to the Circuit Supervisor as needed.

c. Notifies State officials, inspectors in charge, producers, integrated operations, and official establishments of case progress as delegated by the Regional Director.

d. Receives information about industrial, farm, and packing plant accidents, natural disasters and other incidents suspected to cause chemical residues in animals and/or products. Sources providing information include inspectors in charge, other government agencies, industry, consumer or the news media.

e. Notifies regional office immediately by telephone.

f. Follows action plan provided through the region.

g. Provides regional office with cost accounting information for Alert or Action cases as directed.

6. **Circuit Supervisor** - General Responsibilities:

a. The Circuit Supervisor is responsible for operation of CRS procedures by inspection personnel within the circuit and for performing the following tasks during routine and special assigned plant visits.

b. Review implementation of case followup actions by SVMO including:

(1). Information exchange with area/region.

(2). Information exchange with plant management.

(3). Livestock/poultry and product identification, control, sampling, and disposition procedures.

(4). Recordkeeping and filing.

c. Provides guidance, assignment of personnel and other necessary actions to ensure correct implementation.

7. **Supervisory Veterinary Medical Officer** - General Responsibilities:

a. The SVMO provides supervision necessary to accomplish followup sampling and other plant level responsibilities in accordance with plan prepared by the Regional Residue Staff Officer.

b. Collects case history information as directed.

c. Selects and identifies animals or carcasses for sampling as described in Attachment 2.

d. Collects tissue specimens as described in Attachment 3.

e. Prepares tissues specimens as described in Attachment 4.

f. Completes FSIS Form 10,000-2 as described in Attachment 5.

g. Mails specimens in shipping container 1 working day after tissue specimen is frozen solid.

h. Receives oral and written information on test results, product dispositions, and followup actions from region or area offices, and communicates this information to establishment management as directed.

i. Maintains a case file which includes returned forms and directions from region until notified the case is closed.

j. Receives information about industrial, farm and packing plant accidents, natural disasters and other incidents suspected to cause chemical residues in animals and/or products. Sources providing information include packing establishment workers and management, producers, consumers, the news media, and ante-mortem or post-mortem examinations.

(i). Notifies area office immediately of case progress by telephone.

(ii). Follows action plan provided through the region.

k. Provides region with cost accounting information for Alert or Action cases as directed.

If there are any questions regarding this directive, please use the normal channels of contacting the regional offices.

Administrator

Attachments

1 -- CRS Residue or Compound Identification Chart
2 -- Specimen Selection Instructions for SVMO
3 -- Tissue Specimen Sites and Sizes
4 -- Instructions for Specimen Preparation for Shipment
5 -- Instructions for Completion of FSIS Form 10,000-2 and Example of Form

CRS RESIDUE OR COMPOUND IDENTIFICATION CHART

COMPOUND CODES	COMPOUNDS
100	**CHLORINATED HYDROCARBONS**
101	Aldrin
102	Benzene Hexachloride
103	Chlordane
104	Dieldrin
105	DDT & Metabolites
106	Endrin
107	Heptachlor & Metabolites
108	Lindane
109	Methoxychlor
110	Toxaphene
111	PCB
112	Hexachlorobenzene
113	Mirex
114	Strobane
115	Nonachlor
116	Octachloro Dibenzodioxin
117	Heptachloro Dibenzodioxin
118	Hexachloro Dibenzodioxon
119	Tetrachloro Dibenzodioxin
124	P,P-DDT
125	O,P-DDT
126	P,P-DDE
127	O,P-DDE
128	P,P-TDE
129	O,P-TDE
150	Kepone
152	Endosulfan I
153	Linuron
154	Phosalone
155	Pentachloromethoxybenzene
	CHLORINATED HYDROCARBONS
161	Paradichlorobenzene (p-Dichlorobenzene)
162	Tetrachloroethylene
181	Halowax
191	PBB

192	Ethylene Dibromide
200	**ANTIBIOTICS**
203	Chloramphenicol
300	**ORGANOPHOSPHORUS PESTICIDES**
301	Coumaphos & Oxygen analog
302	Dichlorvos
303	Diazinon
304	Ethion & Oxygen Analog
305	Malathion
306	Parathion
307	Ronnel
308	Crufomate
309	Trichlorfon
310	Methyl Parathion
311	Dioxathion
312	Disulfoton
313	Fenetrothion
314	Stirofos
315	Chlopyrifos
316	Fenthion
318	Carbophenthion (Trithion)
319	Azinphos-Methyl (Guthion)
320	Chlorfenvinphos
361	Ethion Metabolite
362	Coumaphos Metabolite
363	Chlorpyrifos Metabolite
371	2-Ethylhexyldiphenyl Phosphate
	TRACE ELEMENTS
402	Mercury
403	Copper
404	Lead
405	Zinc
406	Cadmium
408	Selenium

	CARBAMATES
602	Aldicarb & Metabolites
604	Propoxur (Baygon)
605	Carbofuran & 3 Hydroxycarbofuran
606	Methiocarb and its metabolite - Sulfoxide
607	Bufencarb
608	Methomyl
609	Chloropicrin (Larvicide)
621	Cyromazine (Larvadex)
622	Melamine
650	Nitrogen Pesticides
652	Amitraz
700	**HERBICIDES**
701	2,4-D
702	2,4,5-T
704	Bromoxynil
705	Dicamba
706	Silvex
707	Triclopyr
720	**CHLORINATED HERBICIDES**
721	Dichlorophenol
722	Tetrachlorophenol
723	Pentachlorophenol

NOTE:

* This chart does not include all CRS compounds or environmental contaminants.

** Eighty percent of the residue limit for each compound will initiate a Contamination Response System (CRS) case.

SPECIMEN SELECTION INSTRUCTIONS FOR SVMO

The SVMO will receive notice from the regional office when restricted animals/birds affected by an on-going surveillance or CRS residue case are due for slaughter.

The SVMO will alert plant management to identify the restricted lot prior to ante-mortem and post-mortem inspection.

Select specimens according to the specific residue case instructions provided by the regional office.

Collect identification information including:

1. Hide or horn brands
2. Ear or back tags
3. Tattoos
5. Lot identification devices used by packer

When adulteration by residues is suspected in animals/birds or products not covered by existing residue case, the following steps will be taken:

1. Hold suspect animals/ birds (live if possible), and products.
2. Contact the regional office for assistance.

TISSUE SPECIMEN SITES AND SIZES

I. Tissue Codes:

Fat	01	Kidney	04
Liver	02	Urine	D3
Muscle	03	Other	06

II. Preferred Specimen Location:

Tissue	**Red Meat**	**Poultry**
Fat	Kidney fat	Abdominal fat, on thin birds also include skin and tail
Muscle	Pillars of diaphragm	Thigh with skin and bone removed

III. Preferred Specimen Amount:

Tissue	Collect From **1 Red Meat Animal**	Collect From **1 Bird or Rabbit***
Fat	1 Pound (450 grams)	2 to 3 oz. (55-85 grams)
Liver	1 Pound " "	Entire liver
Muscle	1 Pound " "	2 to 3 oz. (55-85 grams)
Kidney	1 Pound " "	Entire kidney

*Sample 6 Birds/Rabbits and pack separately

IV. Tissues Normally Requested for Commonly Tested Compounds

Compound/Class	**Tissue Codes**	**Compound/Class**	**Tissue Class**
Antibiotics	2,3,4	Halofuginone	2,3
Arsenic	2,3	Ivermectin	2,3
Benzimidazoles	2,3	Pyrethrins	1

Carbadox	2,3	Sulfonamides	2,3
Carbamates	1,2,3,4		
Chlorinated hydrocarbons/chlorinated organophosphates	1		

SPECIMEN PREPARATION FOR SHIPMENT

A. **Tissue Specimen Preparation** - FSIS or Contract Laboratory

1. Place a tissue specimen from one animal or bird into a plastic bag. (See 3)

2. Expel excess air, twist top of bag and close with rubber band.

3. Prepare specimen labels. For enforcement samples print tissue type, individual sample number and FSIS Form 10,000-2 serial number on a paper strip with pencil or water resistant ink. For monitoring samples the completed tear strip provides comparable information.

4. Place bagged specimen into a second plastic bag, along with the paper strip with writing facing outward, expel excess air, twist and close with rubber band.

5. Repeat this bagging and labeling procedure for each tissue specimen type required from each animal or bird.

6. Complete FSIS Form 10,530-1 (Monitoring) or FSIS Form 10,000-2 (Enforcement Testing).

7. Place bagged sample into inspection-secured area of freezer. Do not freeze specimens directly in the insulated shipping container; delayed cooling might result in damage to specimens.

8. Write down date and time sample was placed into freezer and post conspicuously in FSIS inspection office.

9. When tissue is solidly frozen, normally on the following workday, complete assembly of the shipping container, including addition of prefrozen coolants. Ship using the designated carrier following directions provided by the Regional Director.

B. **Tissue Specimen Preparation** - FSIS and Accredited Laboratory; Special Procedures.

1. Consult with the Regional Residue Officer through normal supervisory channels for current accreditation status of the proposed laboratory or for guidance in determining the availability of accredited laboratories and their capability to confirm violative findings. The laboratory must be accredited for the specific compound.

2. FSIS must maintain custody of all tissues during specimen preparation. Collect or observe official plant collection of split specimens to provide tissue for accredited laboratory and for FSIS quality assurance testing.

3. Poultry and Rabbits: For each bird/rabbit, collect twice the normal amount of muscle and split in half. Split livers and kidneys roughly in half. Use one portion of the specimen for the FSIS lab and the other portion for the accredited laboratory. If insufficient tissue is available, consult with the Regional Residue Officer for options to avoid compromising the sample plan.

4. Red meat species: Collect twice the normal amount of each required tissue and prepare matched representative samples as follows:

a. Cut an estimated 1 ounce piece from the double sized specimen and place in a sample bag identified for the accredited laboratory.

b. Cut a neighboring piece, also about 1 ounce in size from the same specimen and place in a sample bag identified for the FSIS laboratory.

c. Continue cutting and placing alternate pieces in the two bags until pairs of normal sized chopped representative samples have been accumulated from the original tissue specimen.

d. Bag and label, maintain security, secure, record time, and freeze the split specimen as described in A above.

5. Refer to 3 for logging split specimens and completing the FSIS Form 10,000-2.

6. The establishment will provide appropriate shipping containers and transportation for the split specimens going to the accredited laboratory. For these specimens to maintain their official status, they must be suitably sealed or maintained in

FSIS custody until turned over to Federal Express or other carrier for shipment to the laboratory. Refer to FSIS Directive 7355.1 for use of sample seals.

7. Prepare the FSIS components of each specimen pair in the conventional manner, using identical labels as used for the components going to the accredited laboratory. Follow split specimen procedures covered in Attachment 5.

PREPARATION AND DISTRIBUTION OF FSIS FORM 10,000-2, DOMESTIC LABORATORY REPORT

A. Use one 10,000-2 packet for each of the following:

1. Each animal to be tested individually:

   Example: One Form 10,000-2 for the individually bagged and identified kidney, liver and muscle from one hog.

2. Each group of animals with specimens that will be composited in the laboratory:

   Example: One Form 10,000-2 for the individually bagged and identified fat from each of 6 chickens to be composited in the laboratory.

3. Split specimens meeting either of the above criteria and going to an accredited lab and FSIS lab. Note special distribution instructions on back of Form 10,000-2 for splitting the Form 10,000-2 packet between the two labs.

B. Blocks 1 & 5: Are not for inspector use.

C. Block 9 - Condemned Tag No: If applicable.

D. Block 10 - Project Name:

   Enter "INSP" for VMO/inspector independently initiated testing.

   Enter project name, if provided by region, for region or headquarters initiated sampling, including case actions.

E. Block 11 - Case Number: Enter RVIS Residue case number if one exists.

F. Block 12 - Related Serial Nos:

Include the Form 10,000-2 serial number(s) for other specimens collected at the same time from the same herd or flock. Use "Block 24" if space is needed for supplemental information.

G. Block 15 - Technical Support Lab:

When Science and Technology, FSIS assigns a contract lab, check the designated square and record the lab name. A "contract lab" is a non-FSIS laboratory under contract with FSIS to perform official tests. (Do not confuse with "accredited lab.")

When the packer elects to use an accredited lab, check the square identifying the FSIS lab sharing split specimens with the accredited lab. Refer to Block 19.

H. Block 16 - Name and Address of Producer, Herd, or Flock Owner:

Integrated Operations - Also record the name, address and zip code of the integrated operation.

If owner ID is not obtainable at the plant, record name of buyer/dealer/auction market or other source that is available.

Use Block 24 if more space is needed.

I. Block 17 - Species & Block 18 - Species Code:

Record the slaughter species/class descriptive name and code in block 17 and 18 respectively. The codes must match the table as described on the reverse side of FSIS Form 10,000-2. Occasionally, the slaughter class is difficult to determine, especially after hide removal. When in doubt, enter name and code for the most likely slaughter class and explain in block 24.

J. Block 19 - Accredited Lab Name:

Record name and address of accredited lab when used for official testing by packer. An accredited lab is a non-FSIS laboratory approved by FSIS to perform specific official tests at industry option and expense

for purposes of product disposition. Verify with the Regional Office through established channels first. Prepare split specimens to share with the designated FSIS laboratory for quality assurance testing. The accredited lab test results are sent to the regional residue officer and are used for disposition purposes. FSIS testing of split samples is done on a skip lot basis and is used as part of an ongoing quality control assessment of the accredited lab. Refer to Block 24 instructions below and special distribution information on back of Form 10,000-2.

K. Block 20 - Split Sample No:

Applies to split specimens shared by an accredited lab and FSIS lab. The SVMO of a plant using an accredited laboratory is required to prepare a record of all split specimens. The first split specimen is numbered 001. Subsequent split specimens are given the consecutive 3 digit numbers 002, 003 and so on. The following is an example of a method to generate consecutive split sample numbers. The record can be continued until 999 samples have been recorded before starting with 001 again. Other formats that will generate and record consecutive sample numbers are suitable.

Residue Split Sample Record - Establishment No: 38X					
Number	Col.Date	Acc. Lab.	FSIS Lab	10,000-2	Inspector
001	4/5/92	ABC Inc.	MWL	000123	I.Good DVM
002	5/7/92	Tech Ltd.	EL	123456	D.Best
etc.	etc.	etc.	etc.	etc.	etc.

Record in block 20 the consecutive 3 digit number from the Accredited Laboratory Record. The Split Sample Number and the Form 10,000-2 Serial Number are used by Science and Technology to link the findings from the two laboratories for quality control purposes.

L. Block 21 - Residue Class Code/Specific Residue:

Check the "Residue" box and enter the general residue class code followed by the code for the specific

residue suspected. Reference the table of residue class codes on the back of Form 10,000-2 and individual residue codes in Attachment 1. If additional space is needed to enter multiple residue classes, use any open space in Block 21.

M. Block 23 - RVIS DATA:

Tag Numbers/Tag Types:

Enter all available identification device information for all animals sampled (not just RVIS Cases). Use block 24 if additional space is needed.

"Tag Types" include but are not limited to: Tatoos, brands, tail tags, MCT (market cattle testing) tags, sales tags, bangle tags, ear tags, and back tags.

Follow-up Sample:

Check "Yes" - if this specimen is for an ongoing residue case and the producer/responsible party complied with the FSIS slaughter notification request in the case letter.

Check "No" - if this specimen is for an ongoing residue case and the producer/responsible party did not notify FSIS as requested.

F/U Form No: Leave Blank.

F/U Source ID: Leave Blank.

N. Block 24 - Related Information:

Enter information to supplement entries in other blocks, including, but not limited to:

Animal ID documentation:

Lot (flock/herd) sizes, lot (flock/herd) ID numbers and names, color, breed, live weight, dressed weight, age or other unique characteristics to help identify animals, especially when conventional ID devices are inadequate.

Identification of specimens, lab directions and reference to other forms:

Example: "Specimens from birds 12 through 18 for compositing in lab. Part of 30 bird test. Related form numbers: 123451, 123452, 123453, 123481."

O. Blocks 25, 26, 27 - Name, Badge Number & Telephone Number:

Type or Print to assure legibility. These entries facilitate consultation if questions arise.

P. Distribution of Form - No accredited laboratory used:

To FSIS or contract laboratory:

Send entire packet minus parts 4 and 5, protected in a plastic bag, to the laboratory in the specimen shipping container.

To regional office or area office:

When designated by specific programs or upon request from the regional director, send part 4 to the designated location.

For inspector's file:

For inspection office file at establishment.

Q. Distribution of Form - Accredited & FSIS laboratory - split specimens:

To accredited laboratory:

Send parts 1 and 2 protected in a plastic bag, to the accredited laboratory in the specimen shipping container. The packer is responsible for providing the shipping container and payment for transportation to the laboratory. Ensure sample security by maintaining custody until pickup by the carrier or by use of sample seals.

To FSIS laboratory:

Send parts 3 and 4 protected in a plastic bag, to the designated FSIS laboratory in the specimen shipping

container. Do same for all slaughter inspection residue specimens involving accredited laboratories, unless a skip lot procedure is provided, through the regional office, on an individual case basis.

For inspector's file:

For inspection office file at establishment.

NOTE: The part completed by the FSIS laboratory is for Science and Technology quality control use and is not normally returned to Inspection Operations.

Form OMB Approved: 0583-0015

1. INTERNAL LAB NUMBER

USDA - FSIS
SCIENCE AND TECHNOLOGY
DOMESTIC LABORATORY REPORT
(READ INSTRUCTIONS ON REVERSE OF PART 5 BEFORE COMPLETING)

NUMERIC CODES: 2. STATE | 3. REGION | 4. AREA

5. TYPE SAMPLE | 6. SERIAL NO.

7. ESTABLISHMENT NO. | 8. RETAIN TAG NO. | 9. CONDEMN TAG NO. | 10. PROJECT NAME | 11. CASE NO. | 12. RELATED SERIAL NOS.

13. DATE SAMPLED | 14. DATE MAILED | 15. TECHNICAL SUPPORT LAB ☐ Eastern Lab ☐ Western Lab ☐ Midwestern Lab ☐ Contract Lab Name:

16. NAME AND ADDRESS OF PRODUCER, HERD, OR FLOCK OWNER

Alpha State Code | Zip Code

17. PRODUCT / SPECIES | 18. SPECIES CODE | 19. ACCREDITED LAB NAME | 20. SPLIT SAMPLE NO.

21. REQUEST FOR (*Check*) ☐ Residue ☐ Food Microbiology ☐ Species Identification ☐ Extraneous Materials | RESIDUE CLASS CODE | SPECIFIC RESIDUE

22. TISSUE (*Check*) ☐ 01 Fat ☐ 02 Liver ☐ 03 Muscle ☐ 04 Kidney ☐ 06 Other (*Specify*):

23. RMIS DATA

Tag Number(s)	Tag Type(s)	FOLLOW-UP SAMPLE ☐ Yes ☐ No
		F/U FORM NO.
		F/U SOURCE ID

24. RELATED INFORMATION

SAMPLE COPY

25. NAME OF INSPECTOR (*Type or Print*) | 26. BADGE NUMBER | 27. TELEPHONE NUMBER (*Include Area Code*)

To Be Completed by Inspector (*Except 1 and 5*)

28. FOR LABORATORY USE ONLY

29. CONDITION CODES: RECEIPT	SEAL	DISCARD	30. LAB CODE	31. DATE RECEIVED	32. ANALYSIS DATES: a. STARTED	b. COMPLETED	33. SRC	34. WC

35. SIGNATURE OF ANALYST(S) | 36. ANALYST(S) CODE | 37. REVIEWED BY (*Signature*)

To Be Completed by Laboratory

FSIS FORM 10,000-2 (4/92) REPLACES FSIS FORM 10,000-2 (7/91) WHICH IS OBSOLETE

Part 1 - LABORATORY (Send to Regional Office)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

[ ] DIRECTIVE
[ ] REVISION
[ ] AMENDMENT
[x] OTHER

BLUEPRINT REVIEW POLICY-- QUESTIONS AND ANSWERS	11,150.1	2/2/93

I. PURPOSE

The title of FSIS Directive 11,150.1, dated 10/22/92, has been changed. The attached page contains the new title.

II. CHANGE

The title of FSIS Directive 11,150.1, dated 10/22/92, has been changed to read "Blueprint Review Policy -- Questions and Answers." Please remove the first page of the directive and replace it with the attached page.

III. CANCELLATION

This transmittal sheet is cancelled when the attached page has been incorporated into FSIS Directive 11,150.1.

Nancy E. Soodak

Acting Director
Regulations Development Unit
Policy Office, PEPS

Attachment

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Management, T/A Plant Mgt., TRA, ABB, PRD, AID

OPI: S&T, FESD

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

11,150.1 | 10/22/92

BLUEPRINT REVIEW POLICY -- QUESTIONS AND ANSWERS

I. PURPOSE

This directive transmits a Questions and Answers Guide regarding blueprint and specifications submittal and approvals. There are six sections of questions and answers. The first regards original blueprint and specification submissions and the second, submissions for changes to previously approved blueprints and specifications. The third and fourth sections deal with the appeal and re-submission process and review difficulties, respectively. Section five addresses the monitoring of facilities and, lastly, section six provides some general questions and answers.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Sections 304.2, 308.2, 308.3 and 381.19, 381.45.
FSIS Directives, 11,010.1, 11,100.1, 11,100.2, and 11,140.1.

V. POLICY

The MPI Regulations require that two sets of complete drawings (blueprints) and four sets of specifications be submitted to the Facilities, Equipment, and Sanitation Division (FESD), Science and Technology, prior to a grant of inspection. Approval is based on a review and evaluation of facility blueprint drawings. Additionally, any changes to official establishments must be approved by FESD, however, only the

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OPI: S&T/FESD

*U.S. G.P.O.:1993-341-645:80010/FSIS